DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2016

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive Southeast
Leesburg, Virginia 20175

Re: K150481
Trade/Device Name: Cascadia Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: August 20, 2015
Received: August 20, 2015

Dear Ms. Giezen:

This letter corrects our substantially equivalent letter of August 20, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150481

Device Name
Cascadia Interbody System

Indications for Use *(Describe)*

The CASCADIA implants are indicated for use with autogenous bone graft as intervertebral body fusion devices in skeletally mature patients. The implants are intended for use at either one level or two contiguous levels, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar implants are intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the CASCADIA implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
Cascadia Interbody System
K2M, Inc.

Submitter

K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 571 919-2168
Date Prepared: 08/18/2015

Classification

Trade Name: Cascadia Interbody System
Common Name: Intervertebral Fusion Device with Bone Graft
Regulatory Class: Class II

Classification Name(s):
Intervertebral Body Fusion Device with Bone Graft, lumbar (21 CFR 888.3080, Product Code: MAX)

Predicate Device(s)

Primary Predicate:

- K2M Aleutian IBF Spinal System (K082698)

Additional Predicates:

- K2M Aleutian IBF Spinal System (K110843, K113138, K130699, K133614)
- Zimmer TM Ardis (K113561)
- 4WEB STS (K112316)
- Advanced Medical Technology Fuse (K100945)
- Signus Mobis II ST (K141405)

Device Description

The subject submission describes the Cascadia Interbody System. The implants consist of hollow tube structures made of titanium alloy. The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The purpose of the subject submission is for a line addition to the lumbar intervertebral body fusion devices previously cleared in the K2M Aleutian Intervertebral Body Fusion System, to include implants additively manufactured from titanium alloy.

Function: The system functions as an intervertebral body fusion device to provide support and stabilization of the lumbar segments of the spine.

Indications For Use

The CASCADIA implants are indicated for use with autogenous bone graft as intervertebral body fusion devices in skeletally mature patients. The implants are intended for use at either one

level or two contiguous levels, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar implants are intended to be used in patients who have had six months of non-operative treatment.

For all the above indications the CASCADIA implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

Technological Comparison to Predicate(s)
The Cascadia Interbody System implants were compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems.

Non-clinical Performance Evaluation
Performance evaluations were conducted on constructs representing the worst case components (including static torsion, static compression, dynamic compression, static compression shear, dynamic compression shear (ASTM F2077), subsidence (ASTM F2267) and expulsion) and the proposed implants were found to be substantially the same as predicate devices.

Conclusion
There are no significant differences between the Cascadia Interbody System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.